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In The Claims

Please cancel claims 12, 14 and 25, and amend the claims as follows:

11. (Currently amended) A vascular device for treating a blood vessel with aneurysm comprising:
a tubular graft having a proximal portion and a distal portion;
at least two docking heads comprising thin-walled truncated cones
wherein a first docking head is provided at said proximal portion
and at least one second docking head is provided at said distal
portion and wherein at least one of said at least two docking heads
is movable in respect to said graft and is adapted to be adjusted
and fastened to a suitable positioning on said graft before insertion
of the vascular device to the vessel;
a plurality of outwardly pointing and inclined barbs is connected to at
least one of said at least two docking heads;
wherein the vascular device is capable of being coupled to the blood vessel
on both sides of the aneurysm by said at least two docking heads that act
as guiding, anchoring and sealing means in a suture-less and rapid manner.
12. (Cancelled)
13. (original) The vascular device as claimed in Claim 11, wherein said graft is a
bifurcated graft.
14. (Cancelled)
15. (currently amended) The vascular device as claimed in Claim ~~12~~ 11,
wherein said at least one of said at least two docking heads is coupled to

said suitable positioning by a means selected from a group such as fit, glue, sutures, clips, or staples.

16. (currently amended) The vascular device as claimed in Claim 11, wherein said at least two docking heads have an outer diameter so as to couple the graft to the vessel, and wherein said at least two docking heads comprise a hollow truncated cone having a passage that ~~is adapted to correspond~~ corresponds to an outer diameter of said graft ~~and wherein said truncated cone is provided with a plurality of outwardly pointing and inclined barbs.~~
17. (original) The vascular device as claimed in Claim 16, wherein said hollow truncated cone is elastic.
18. (currently amended) The vascular device as claimed in Claim 16, wherein said hollow truncated cone has a concaved, convex or straight profile ~~adapted~~ corresponding to a profile of said blood vessel in positioning of said at least two docking heads on said graft.
19. (currently amended) The vascular device as claimed in Claim 16, wherein an outer diameter of said hollow truncated cone ~~which is a smaller diameter~~ is of substantially smaller diameter than an internal diameter of the blood vessel so as to guide it into the blood vessel.
20. (currently amended) The vascular device as claimed in Claim 16, wherein a larger diameter of said hollow truncated cone surpasses an inner diameter of the blood vessel so as to assure firm sealing of the vessel in said at least two docking heads positioning in said the vessel in about 1 to 10 mm.
21. (original) The vascular device as claimed in Claim 16, wherein said barbs are flexible and are inclined towards a direction of said graft.

22. (currently amended) The vascular device as claimed in Claim 46 11, wherein some of said plurality of barbs have a length that ~~ranges from 1 to 4 times~~ is substantially longer than the thickness of the ~~a blood~~ vessel's wall so as to enable perforating the vessel's wall.
23. (currently amended) The vascular device as claimed in Claim 46 11, wherein some of said plurality of barbs are bent so as to establish a concave profile in respect to a radial cross section of said hollow truncated cone.
24. (currently amended) The vascular device as claimed in Claim 46 11, wherein some of said plurality of barbs are bent so as to establish a convex profile in respect to a radial cross section of said hollow truncated cone.
25. (cancelled)
26. (original) The vascular device as claimed in Claim 16, wherein said hollow truncated cone is provided with a plurality of open slits adapted to allow said truncated cone to curtail its larger diameter.
27. (original) The vascular device as claimed in Claim 11, wherein said truncated cone is an extension of said tubular graft that is outwardly everted over a guiding end of said at least two docking heads.
28. (currently amended) The vascular device as claimed in Claim 11, wherein said at least two docking heads as well as said graft are made as ~~changeable~~ separate modules that can be selected according to individual blood vessel anatomy ~~to be prosthetic~~ prior to the insertion of the vascular device into the vessel.

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Remarks

By the above amendment, applicant has amended several claims in order to define the invention patentable over the prior art.

Drawings

Claim 25 is cancelled in order to overcome the examiner's observation.

The rejection of Claims 20 and 22 under §103

Claims 20 and 22 are currently amended in order to overcome the rejection in the Office Action. The dimensions are removed from the claims and only substantial material is left. The barbs and the docking head are significantly different from Haverkost as mentioned earlier and the claims now distinctly define the novelty of the claimed invention.

The rejection of Claims 11, 14, 19 and 22 under §101

Claims 11, 19 and 22 were amended in order to overcome the rejection. Claim 14 is cancelled.

The rejection of Claims 12 and 27 under §112

Claim 12 is cancelled.

Since Claim 11 is currently amended, Claim 27 now has the antecedent basis.

Claim objection

Claim 24 was corrected according to the examiner's observation.

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The rejection of Claims 1-15 and 28 under §102

Claim 11 that was rejected in this Office Action have been amended so as to define patentability over Randall (US 2003/0158595) wherein claims 12 and 14 were cancelled and combined to within the amended Claim 11. Claim 28 was also amended. Applicant requests reconsideration of the rejection for the following reasons:

Randall in US 2003/0158595 indeed discloses a bifurcated graft 40; however, this graft is provided with ring stents 10, 16 and 18 (defined as docking heads in the Office Action) that are adapted to be in enlarged or deployed states as explained in Paragraph 0017. Moreover, Randall's ring stents are slender threads (Figures 1 and 2) that are made of a shape memory material (paragraph 0019), which is a metal that can provide the physical requirements of expansion such as explained in the patent. In the claimed invention, the docking head is made as thin walled truncated cone (paragraph 0119; Figure 14) that is adapted to provide the characteristics of guiding, anchoring and sealing the graft as explained at the end of paragraph 0114 and indicated in the "wherein clause" of Claim 11. The ring stent of Randall can not perform in those three functions due to its structure and its shape transformation and is indicated to be "an anchoring device" solely. Therefore and in order to overcome the Office Action observations, the limitations of thin walled truncated cone structure of the docking head as well as the barbs were combined in Claim 11.

In Randall, the stent is indeed movable within the vessel; however, it is adapted to move along and within the graft, and it moves along the graft prior to the expansion of the stent also within the graft. In the claimed invention, the docking head is movable along the graft from its outer surface, rather than the interior as in Randall. Additionally, the docking head of the present invention is connected to the graft before the insertion of the graft to within the vessel. Although the

docking head and the graft are introduced as separated modules, they are connected to each other by means stated in Claim 15 before the insertion of the graft to within the vessel. The two modules are selected before the insertion to the vessel in order to accord the graft and the docking head to the specific vessel and are connected to each other before the insertion itself. They are not introduced into the vessel as separated modules as in Randall.

Regarding claim 15, the ring stent of Randall is not connected in any way to the graft. It is indeed movable along the graft, but it moves along its interior and holds the graft in place through the force of expansion. In the claimed invention, the docking heads are not extended onto the graft and the vessel, and they are connected to the graft in an appropriate position that can be determined during or before the treatment.

Claim 28 was amended according to the previous remark that is relevant to this Claim as well.

Elliot (US 2003/0346567) discloses a skirt that is an extension of a tubular body. This is especially the case shown in Figures 3a-c, which are specifically indicated in the Office Action. In the claimed invention, the docking head (parallel to Elliot's skirt) is a separated module that is connected to the graft and not an extension. Elliot, as disclosed in paragraph 0029 discloses a connection to the vessel that is formed through expansion pressure and not through connection using barbs as indicated in amended Claim 11. Moreover, Elliot in paragraph 0030 and Figure 3c discloses a scaffold 22 that supports the skirt "the scaffold 22 preferably includes a plurality of circumferentially-spaced tines which are self-expanding either due to inherent spring action and/or due to memory properties...". The docking head of the claimed invention is a self supporting element that forces the vessel to gain its shape rather than being shaped according to the vessel such as in Elliot.

Elliot fails to disclose any barbs so as to connect the vessel to the skirt and seal the connection. The fixation of the docking head of the claimed invention to the vessel is through the barbs and not through expansion as in Elliot.

Claim 12 is already cancelled. Claims 15 and 27 are now dependent on an amended Claim 11 that defines novelty over Elliot.

Haverkost (US 2003/0074055) discloses collar stents (docking heads) that are being implanted within the vessel (Figure 2) before the graft is being inserted into the vessel. In opposition to what is stated in the Office Action, the collar stents are not moving relative to the graft, the graft is moving relative to the stents after the stents are implanted within the vessel, as stated in Paragraph 0031 "...The method comprises preconditioning the lumen prior to implantation of the endoluminal device by implanting one or more collar stents, and then deploying the endoluminal device on top of the collar stents....". Moreover and as stated in Paragraph 0034, the collar stents are preferably implanted about 2 weeks prior to the implantation of the graft "to allow sufficient intravascular tissue growth." This is totally opposed to the docking head of the claimed invention in which the two modules are being connected prior to the implantation and are being inserted together to the vessel. However and in order to overcome the examiner's observations, Claim 11 was amended and according to amended Claim 11, the docking heads are mounted so as to move along the graft and is adapted to be fasten to a suitable positioning on the graft before insertion of the vascular device to the vessel. Moreover, the collar stents of Haverkost, similarly to Randall, are "typically a bare (non-covered) wire stent" Rather than a thin-walled truncated cone as claimed in this application.

Regarding the barbs that are provided to the stent, there is an option that is disclosed in Haverkost, in which "the stent may have a plurality of barbs (not shown) that protrude radially outward for enhanced fixation of the collar to the

body lumen, as are known in the art". The barbs in this application are for enhanced fixation while the barbs of the claimed invention are forming the fixation rather than enhancing it. There will be no firm connection between the docking head and the vessel (at least in the distal portion) without the barbs since the docking head does not have any expansion properties such as the spring properties of Haverkost as well as Randall's stents. Moreover, the barbs in the claimed invention are not radially protruding such as in Haverkost case and as known in the prior art (as stated by Haverkost) and therefore, are distinctly novel (claimed to be inclined in Claim 11). The inclined claimed barbs allow forward movement of the graft within the vessel in its original diameter, which is also substantially its final diameter. In the prior art – the docking head is expanding, therefore pushed radially to the vessel. Radial barbs are stacked to within the vessel. In the claimed invention, the barbs are stacked to the vessel upon withdrawing the graft outwardly off the vessel, and therefore, the direction of the barbs is premeditated to this movement. As indicated in the specification paragraph 0130 – "After the positioning of the guide in the healthy neck in the proximal side of the vessel, the proximal side of the graft 210 is placed within the corresponding neck while pulled slightly outwardly in order to nail barbs 212 of docking head 214 in the distal neck."

Regarding the conical structure of the stents; in opposition to the Office Action, in Figure 5 as well as Figure 6 and other figures of Haverkost, straight profiled stents are shown that are forced by expansion (indicated also by the Office Action) to the vessel. Specifically in Figure 5, the conical structure is formed by tissue that grows into the gap between the stent and the vessel as indicated in paragraph 0034 of Haverkost: "...By first placing collar stent 30 in neck 20 and allowing intravascular tissue growth 46 between the lumen walls and the collar, the available fixation length in the neck is, in effect, lengthen." From this explanation, it is understood that the length of the stent that is in actual contact with the vessel

is relatively short while in the claimed invention, it is lengthened due to the conical structure.

Regarding Claims 12-15, arguments were already given in reference to Randall.

In Claims 16-19 there are specific limitations of the amended claim 11 that now define novelty over Haverkost as well as other prior art.

Regarding Claim 21, as mentioned herein before, Haverkost's barbs are radial, in opposition to the inclined barbs of the claimed invention. Claim 21 specifically claims the preferred direction of inclination of the barbs. Flexibility or other characteristic of Haverkost's barbs are not mentioned at all.

Regarding Claim 23, the specific shape of Haverkost's barbs is not disclosed or addressed at all.

Regarding Claim 26, the materials and the characteristics of the stent of Haverkost and the claimed docking head are so different that the slits that are formed in the docking head only provide slight expansion properties while the wired structure of the stent provides it with expansion properties that are not needed in the claimed invention. The extent of curtailing is totally different for the two materials and needs.

Regarding Claim 28, the argument was already given in reference to Randall.

The docking head of Baker et al. (6,729,356) comprises two members – an attachment system (138 in Figures 5-7), embodying modulating or flat wire, and a sealing member (140) (column 6, lines 16-24). The tubular member and the sealing member are positioned in first compressed conditions (Figure 6) to facilitate packing the graft into a delivery tube device (explained in column 6, lines

36-54). It is understood that the attachment system is for anchoring the device, the sealing member is for sealing and the wires are for compressing the graft in order to be guided to within the vessel. The vascular device of the claimed invention (Claim 11) comprises a docking head that is designed to perform all those tasks – guiding, anchoring and sealing – in one member. As explained herein before, the attachment of the docking head in the claimed invention is by matching the docking head to the vessel and not by expansion as described also by Baker et al. The hooks of Baker et al. merely enhance the attachment between the attachment system and the vessel and not form the connection and sealing as in the claimed invention. The attachment as stated in the Office Action in Baker et al. is upon expansion.

The sealing member as described in Column 2 lines 35-42 in Baker et al. and as stated in the Office Action is indeed a conical structure, however, this conical structure is not provided with barbs, the barbs are provided in the attachment system (36, 136). The conical sealing member is expanded and pressed onto the vessel by the inside wires that impart expansion characteristics to the sealing member rather than elasticity that is provided from the Dacron material that embodies the wires. The wires have springing characteristics that govern the behavior and performance of the sealing member. The conical structure of the claimed docking head that is provided with the barbs impart the sealing and anchoring characteristics of the individual member.

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Conclusion

For all of the above reasons, the applicant submits the Drawings and the Claims are in proper form and the Claims are now defined patentable over the prior art. Therefore, the application and all claims are now in condition for allowance.

Respectfully submitted,



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